University of Pittsburgh
COVID-19 Standards and Guidelines: Human and Animal Research Subjects

I. Purpose

This document details the University of Pittsburgh's (University) Standards and Guidelines on research subjects. These Standards and Guidelines are applied to each of the University's COVID-19 operational postures (High Risk, Elevated Risk and Guarded Risk). More information on these operational postures and their gating criteria can be accessed at the following website: https://www.coronavirus.pitt.edu/operational-postures.

The Standards and Guidelines outlined below are subject to change as deemed necessary by the Senior Vice Chancellor for Research recommendation to the University's Senior Leadership Team and approval of the chancellor. Communication about the University's current Standards and Guidelines will be announced and posted on the following website: https://coronavirus.pitt.edu/.

The University will always operate in compliance with federal, state and local health standards and restrictions, including Pennsylvania Department of Health guidance. The University reserves the right to implement additional health standards and restrictions that reflect the needs of the University and the health, safety and well-being of its community.

The existing policies and procedures for research participants established by the Human Research Protection Office (HRPO)[1] and the Institutional Review Board (IRB) remain in effect, as do the existing policies and procedures for animal subjects established by the Institutional Animal Care and Use Committee (IACUC).[2]

As conditions and circumstances change, this set of Standards and Guidelines may need to be revised.

II. Scope

The Standards and Guidelines below apply to the entire University, including all University members and campuses.

[1] http://www.irb.pitt.edu/content/policies-and-procedures
[2] http://www.iacuc.pitt.edu

III. Definitions

A. Animal subjects: Any live, vertebrate animal used or intended for use in research, research training, experimentation or biological testing or for related purposes.

B. Priority Research Activities: As described in the Research Operations Prioritization Standards and Guidelines, research activities that are allowed to continue during all three operational postures:

a. research on COVID-19;
b. work for which a stop or delay could cause harm to research participants' well-being;
c. work for which a stop or delay could cause harm to animal populations or other vital living collections;
d. work whose suspension would cause a critical loss of unique or irreplaceable materials or data;
e. management of equipment, instruments or research infrastructure where the lack of maintenance could create damage or endanger safety;
f. or work for which a stop or delay would adversely impact critical national security efforts as described in the Department of Defense's Defense Industrial Base Essential Critical Infrastructure Workforce memorandum or disrupt other essential critical infrastructure operations as described by the Director of the U.S. Cybersecurity and Infrastructure Security Agency in the March 19, 2020 guidance on the COVID-19 response.

C. Research participant: A human subject,[3] more commonly referred to as a research participant, is a living individual about whom an investigator (whether faculty, staff or trainee) conducting research (*i.*) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies or analyzes the information or biospecimens; or (*ii.*) obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.

IV. Guidelines for Working with Research Participants

The benefits of both approved and new research protocols involving research participants must be measured against the risk to participants and staff, including the risk of exposure to COVID-19.

All new protocols involving research participants will be evaluated according to HRPO processes in place at the time of submission. For any approved studies involving intervention or interaction with individuals, IRB requires investigators to triage each of their studies into one of three categories:

- **Tier 1:** These are protocols with **high direct benefit** to research participants or that may have a high public health priority, including all protocols involving or about COVID-19

[3] 45 CFR 46

and protocols in which serious or immediate harm could be caused to the research participants if stopped.

- **Tier 2:** These are protocols with **moderate direct benefit** to research participants which, if stopped, may pose a risk to the research participant.
- **Tier 3:** These are protocols with **low direct benefit** to research participants and other impacts to research. Basic research studies that do not directly benefit participants, or those that present a heightened risk because they require participant travel or target participants with high susceptibility to COVID-19 are included in Tier 3. Research with healthy volunteers is included in Tier 3.

Studies that require neither in-person interventions nor interaction with individual research subjects (e.g., chart reviews, online surveys) as well as studies where the only activity is data analysis or long-term follow up (checking for survival status or accessing information from medical records collected during clinical visits) can be performed remotely and therefore may continue under all three operational postures.

The sections below outline the University's requirements regarding guidelines for studies involving in-person intervention or interaction with individual research subjects for each of the University's operational postures. Note that investigators do not need to submit IRB surveys and petitions every time the operational status changes. Protocols reviewed by the IRB for conduct at the High or Elevated Risk Postures may continue when the University's operational posture is reduced to any less restrictive posture. Should the operational posture become more restrictive, investigators may continue all activities that were previously approved for the more restrictive risk status without a new petition or survey submission to the IRB.

A. High Risk Posture

In-person research involving research participants is limited to Priority Research Activities as identified by deans (on the advice of department chairs), institute directors or regional campus presidents, in accordance with the Research Operations Prioritization Standards and Guidelines. Enrollment is paused for all three tiers of in-person studies except for those protocols granted an exemption by the IRB.

Research in Tier 1 can continue if the PI has documented procedures in their Conduct of Research plan demonstrating that the research can be conducted in a safe manner that protects subjects, researchers, and the community. Tier 1 protocols may continue in-person activities with existing subjects but must petition the IRB for enrollment of new subjects. If not done already, self-assessed Tier 1 protocols must register with the IRB through the Reportable New Information (RNI) process in PittPRO if the PI intends to continue in-person activities even if the study will not enroll new subjects at the time.

Research in Tier 2 must cease in-person interactions but may continue interactions with existing subjects remotely. PIs must pause enrolling new research participants into Tier 2 studies. PIs may petition the IRB if they have a compelling reason to continue in-person interactions for existing subjects. Approved in-person contact will be limited to the minimum necessary.

Research activities in Tier 3 must not enroll new participants in studies requiring in-person interaction nor continue to conduct in-person visits. Online visits or data collection that does not require participant interaction may continue. PIs may petition the IRB if they have a compelling reason to continue in-person interactions or conduct in-person enrollment.

B. Elevated Risk Posture

In-person activities involving research participants may continue for Tier 1 studies with [a.] IRB approval to continue enrollment or [b.] registration with IRB to continue in-person activities for existing subjects during High Risk Posture as described above. Tier 2 and 3 studies requiring in-person research activities need to complete one IRB survey, Decision Tree to Determine Human Research Start-Up, per protocol.

After receiving IRB approval, investigators may resume operations once individual faculty/PI Conduct of Research plan and checklist have been reviewed and approved by the dean, institute directors, regional campus presidents or their designees (e.g., associate deans for research or department chairs).

C. Guarded Risk Posture

All in-person research involving research participants may continue.

When the University's operational posture moves from the Guarded Risk Posture to the Elevated or High Risk Posture, studies that have not previously completed the procedure for that higher risk posture will have to complete the procedure as described above for that operational status.

PIs should submit protocol exception requests or modifications to the IRB for any changes to study procedure or consent necessitated by changes in the University's operational posture.

V. Guidelines for Working with Animal Subjects

The Division of Laboratory Animal Research (DLAR) policies during the COVID-19 pandemic are designed to continue outstanding care of all research animals while allowing important animal research to continue. DLAR policies and guidelines take into consideration COVID-19 risk, risk mitigation and protection of both animals and personnel. The following guidelines will be in place during each operational posture:

The requirements in this section assume adherence to all Standards and Guidelines on face coverings, personal hygiene and physical distancing. All housing and procedure rooms must be scheduled in advance and maximum occupancy for each room must be followed. Permission to begin research projects must be obtained from the appropriate dean, institute director, or regional campus president.

When a University campus is in a High Risk Operational Posture, DLAR may place additional restrictions on access to animal facilities, animal breeding and experimentation conducted on that campus. Details for the High Risk operating posture mitigation policies will be posted on the DLAR website: https://web.dlar.pitt.edu/uploads/file/b745988750304e8f8f97fa067c28bf40/DLAR_Guidelines_for_High_COVID-19_Risk.pdf.

Details for the Elevated and Guarded Risk mitigation policies will be posted on the DLAR website: https://web.dlar.pitt.edu/uploads/file/7125fc24682c4b60ba8bca07c7abd754/DLAR_Guidelines_for_Guarded_and_Elevated_COVID-19_Risk_Levels.pdf

VI. Related Authorities, Guidance and Resources

University's COVID-19 Operational Postures and Gating Criteria
Human Research Protection Office (HRPO) and Institutional Review Board (IRB)
Institutional Animal Care and Use Committee (IACUC)
Division of Laboratory Animal Resources

VII. Contact Information and Public Accessibility

This document is posted on the University of Pittsburgh COVID-19 Standards and Guidelines website and can be found at: https://www.policy.pitt.edu/university-policies-and-procedures/covid-19-standards-and-guidelines. For questions related to research participant research, contact askirb@pitt.edu. For questions related to animal subject research, contact iacuc@pitt.edu.